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IN THE

Supreme Court of the United States

OCTOBER TERM, 1985

FRANK YOUNG,
COMMISSIONER OF FOOD AND DRUGS,
Petitioner,

v.

COMMUNITY NUTRITION INSTITUTE, *et al.*,
Respondents.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the District of Columbia Circuit

BRIEF OF AMICUS CURIAE NATIONAL FOOD PROCESSORS ASSOCIATION IN SUPPORT OF PETITION FOR WRIT OF CERTIORARI

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STATEMENT OF INTEREST OF AMICUS CURIAE

Amicus submits this brief in support of the petitioner Frank Young, Commissioner of Food and Drugs. Consent to file this brief has been obtained from counsel for all parties and has been filed with the Clerk of this Court.

The National Food Processors Association ("NFPA") is a scientifically based trade association representing almost 600 member companies that pack a broad range of processed-prepared food products for distribution throughout the country and the world. A substantial portion of these processed products are prepared from fruits, vegetables, and other raw agricultural commodities which in their growing state are exposed to unintended and unavoidable contaminants in the natural environment and which thereby contain extremely small but detectable levels of any number of such environmental contaminants that generally cannot be removed by processing operations. The detection, identification, and possible reduction of these environmental contaminants in raw and processed foods has for many years been an important aspect of the work carried on in the three scientific laboratories of NFPA.[1]

The food processor members of NFPA and the Association itself would thus be very substantially affected by an interpretation of the Federal Food, Drug, and Cosmetic Act, as amended, 21 U.S.C. §§ 301-392 (1982) ("the Act") that regards as adulterated all foods containing detectable amounts of any unavoidable environmental contaminant unless and until a formal tolerance has been established for

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[1]The Association was founded in 1907 as the National Canners Association, growing out of the collective canning industry support for enactment of the Food and Drug Act of 1906. Since its first scientific research laboratory was opened in 1913 the Association has been actively involved in research, testing and training programs that contribute significantly to the safety of the food supply. The Association has continuously maintained its interest in food safety legislation and regulatory programs, including the Federal Food, Drug, and Cosmetic Act of 1938 and subsequent amendments. *See, e.g.*, the references to the involvement of the Association in the 1954 pesticide amendments to the Act, cited in the Government's Petition (Pet. 11-12 n.5).

each such contaminant pursuant to costly, burdensome, and time-consuming evidentiary hearing procedures.

ARGUMENT

Congress in § 406 of the Act, 21 U.S.C. § 346, directed that the FDA "shall promulgate regulations" establishing tolerances for poisonous or deleterious substances required to produce food or unavoidable in its production "to such extent as [it] finds necessary for the protection of public health . . .." The court of appeals read these words as a command to the FDA to promulgate such regulations in any and all circumstances, the qualifying "to such extent" clause conferring discretion only as to the substance of the regulations that must be promulgated. The Government says in its Petition that the court's reading of § 406 is a permissible one, though urging correctly that, even if permissible, the court's reading could not lawfully be substituted for the agency's own permissible, reasonable reading: that Congress has given FDA the customary agency discretion to decide whether — "to [what] extent" — the protection of the public health requires, in any particular circumstance, a formal tolerance regulation. (Pet. 8).

The court of appeals reading is not even permissible unless one improperly isolates § 406 from § 402(a), 21 U.S.C. § 342(a). The effect of the court of appeals reading is to leave the opening clause of § 402(a)(1) — the topic sentence of the whole statutory scheme we are dealing with — without any application. Congress cannot reasonably be taken to have legislated in that way — to have written a statute that states a fundamental rule governing the adulteration of food that might as well not have been stated because all possible cases of adulteration are covered by other more specific rules.

The statutory question presented by the Government's Petition is thus substantial, however the court of appeals

facile "shall-means-shall" reasoning may mask the fact. We explain the substantiality of the question in Part II of the Argument hereunder.

The question is also of the most urgently serious national importance. The court of appeals repeatedly stated that the necessary implication of its decision that the FDA must prescribe formal tolerances for contaminants necessarily or unavoidably added to food was that in the absence of any tolerance, the presence of *any* such necessary or unavoidable substance makes the food adulterated and therefore barred from the channels of commerce. In Part I of the Argument we demonstrate that, if the decision below is allowed to stand, the result will be either an unimaginable and, in fact, insufferable disruption of the nation's food supply or a massive turning of a blind eye to the requirements of the law, with all the impairment of the national respect for law and invitation to selective law enforcement that any such conduct entails.

I. THE QUESTION PRESENTED BY THE PETITION IS OF VITAL NATIONAL IMPORTANCE

Fundamental to the court of appeals decision below is its holding that the presence of an added poisonous or deleterious environmental contaminant in a food renders the food adulterated, unless a tolerance has been adopted under § 406 of the Act.[2] In the final section of its opinion the court

[2]The conclusion by the court that the aflatoxin action level is invalid because the Act does not permit shipment of food containing safe but detectable levels of an environmental contaminant in the absence of a § 406 tolerance is described in the Government's Petition as "one of the two bases for the decision" or as perhaps "dictum." (Pet. 17-18). But the court below left no doubt as to what it regarded as "the issue at hand" — "the FDA's authority *vel non* to allow shipment of adulterated foods without the establishment of tolerances." (Pet. App. 15a). The opinion below is reported at Community Nutrition Institute v. Young, 757 F.2d 354 (D.C. Cir. 1985).

described its holding as follows:

> "[W]e have concluded that the FDA is required to issue regulations establishing tolerances in order for food containing unavoidable added poisonous or deleterious substances to be considered unadulterated for the purposes of 21 U.S.C. § 342(a)(1) . . .." (Pet. App. 15a).

The court *repeatedly* emphasized that FDA's error was to promulgate action levels that purport to permit the shipment of food containing some amount of an environmental contaminant without the adoption of a § 406 tolerance.[3]

This aspect of the opinion below involves a serious misreading of the adulteration provisions of the Act that is at odds with the statutory language, the legislative history, and the agency's long-standing and consistent interpretation of the Act. Further, the court of appeals did not address, or apparently even recognize, the overwhelmingly adverse impact that its interpretation would have on the food industry, the FDA, and the consuming public.

[3]For example: "CNI argues that the Secretary is statutorily obligated to issue regulations embodying a tolerance for the substance before the product may lawfully be introduced into interstate commerce." (Pet. App. 5a). "[T]he statute, in our view, plainly requires the establishment by regulation of tolerances before aflatoxin-tainted corn may lawfully be shipped in interstate commerce." (Pet. App. 7a). Section 306 does not support FDA, because "[t]hat section does not . . . allow the shipment of aflatoxin-tainted corn without the establishment of a tolerance." (Pet. App. 8a). "[W]ithout the tolerance, shipment of the food would not be allowed." (Pet. App. 10a). Cited cases do not support FDA, since they do "not, in our view, speak to the agency's refusal to establish a tolerance while permitting shipment." (Pet. App. 12a). "The court [in *United States v. Goodman*] said nothing as to permission to ship without the establishment of tolerances." (Pet. App. 13a).

Of overriding significance is the fact that virtually all raw agricultural commodities[4] and processed products prepared from them contain one or more unavoidable "added" environmental contaminants, at safe but nevertheless detectable levels. The pivotal term "added" is not defined in the Act, but FDA has consistently maintained that it "is a statutory term of art encompassing all ingredients which are not inherent and intrinsic parts of a food."[5] Accordingly, the FDA regulations define an "added" poisonous or deleterious substance as one that "is not a naturally occurring" substance, and define a "naturally occurring poisonous or deleterious substance" as "a poisonous or deleterious substance that is an inherent natural constituent of a food and is not the result of environmental, agricultural, industrial, or other contamination." 21 C.F.R. § 109.3(c) and (d). That is not a compelled interpretation of the Act. There is a doubtful difference between an inherent part of a food and an "environmental" contaminant such as aflatoxin, which occurs in nature and affects corn because of natural growing conditions. (Pet. App. 3a n.2). The result of the FDA's interpretation is enormously to enlarge the number of contaminants that the agency must deal with as "added" substances. The courts have accepted the FDA's broad definition of the term "added," except that they have required that the contaminant present in the food be attributable at

[4]The term "raw agricultural commodity" is defined in § 201(r), 21 U.S.C. § 321(r), to mean "any food in its raw or natural state."

[5]39 Fed. Reg. 42743 (Dec. 6, 1974). The preambles to the proposed and final regulations dealing with added poisonous or deleterious substances in food set forth at length the basis for the extremely broad scope that FDA attributes to the term "added." *Id.* at 42743-44; 42 Fed. Reg. 52814-16 (Sep. 30, 1977).

least in minute part to the acts of man, whether by deliberate use or by accidental occurrence.[6]

In view of the extremely broad scope of contaminants that are regarded as "added poisonous or deleterious substances," it is not surprising that the FDA regulations take into account the ubiquity and unavoidability of these substances in foods that are raised in or procured from the natural environment:

> "The Commissioner advises that it is not possible to produce food or food ingredients that are entirely free from contamination by foreign substances or impurities." 42 Fed. Reg. 52814 (Sep. 30, 1977).[7]
>
> * * *
>
> "[M]ercury contamination of the aquatic habitat and thereby of fish and shellfish is ubiquitous and unavoidable . . .." 39 Fed. Reg. 42739 (Dec. 6, 1974).
>
> * * *
>
> "If a nondetectable-residue requirement were automatically applied to environmental contaminants al-

[6]United States v. Anderson Seafoods, Inc., 622 F.2d 157, 161 (5th Cir. 1980) (traces of mercury in fish from both natural and human sources regarded as "added"); Continental Seafoods, Inc. v. Schweiker, 674 F.2d 38, 43 (D.C. Cir. 1982) (salmonella in fish held to be "added" on the ground that salmonella "can result" from insanitary processing procedures).

[7]This statement established the factual base upon which FDA relied in promulgating its procedures relating to the regulation of unavoidable environmental contaminants in foods. 21 C.F.R. Part 109. The court below never refers to these FDA regulations or the preambles that set forth their factual and legal basis, in spite of the fact that the specific action levels invalidated by the court of appeals were adopted in explicit reliance on those regulations.

ready present in the food supply, enforcement activities could significantly disrupt the food supply. Removing food containing any detectable residue from the marketplace could lead to enforcement action against food commodities not deemed to present any significant risk to public health." 42 Fed. Reg. 17490 (April 1, 1977).

The action levels actually promulgated by FDA for a broad range of substances and categories of food products are indicative of the pervasiveness of environmental contaminants in the food supply. Aflatoxin is just one of many extremely widespread and unavoidable "added" contaminants that are found in a broad range of agricultural commodities.[8] The Government's Petition lists the environmental contaminants other than pesticide residues for which action levels have been promulgated by FDA. (Pet. 16 n.8). Informal action levels have also been promulgated for a number of unavoidable pesticide residues that are subject to regulation under § 406, including aldrin, dieldrin, BHC, chlordane, DDT, DDE, TDE, DBCP, endrin, fenthion, heptachlor, heptachlor epoxide, kepone, lindane, mirex, toxaphene, and EDB, in one or more of virtually every agricultural commodity.[9] If foods containing these safe but

[8]*See, e.g.*, 39 Fed. Reg. 42748-51 (Dec. 6, 1974).

[9]Section 408, 21 U.S.C. § 346a, provides for the issuance of tolerances for residues of a pesticide in crops for which the pesticide is registered. Unavoidable pesticide residues in non-target commodities are not regulated under § 408, but instead are subject to § 402(a)(1), 21 U.S.C. § 342(a)(1) (and any action levels that may be adopted) or § 406 if a tolerance is adopted. As stated by the FDA in proposing the regulations applicable to unavoidable environmental contaminants, "tolerances or action levels [for pesticide residues] properly recognize the problem of environmental contamination caused by drift of a pesticide from one area to another, or the persistence of the chemical in the environment over a period of time." 39 Fed. Reg. 42745 (Dec. 6, 1974).

detectable levels of environmental contaminants were removed from the market, because of the absence of formally promulgated § 406 tolerances, the impact on the food supply, the food industry, and the consuming public would be so drastic as to be economically and socially intolerable.

Under the reading of the Act advanced by the court of appeals, all shipments in interstate commerce of raw and processed foods containing detectable residues of listed and unlisted environmental contaminants must be deemed to be adulterated and in violation of the Act. The packing, processing, and distributing companies responsible for such shipments will thus be subject to the criminal sanctions of the Act, as will the individual company officials who are deemed to bear a responsible relationship to the violative act.[10] The assumption advanced in the Government's Petition that FDA would not enforce the Act in such a way as seriously to disrupt the food supply (Pet. 18) has a hollow ring to food company officials who have been explicitly warned by this Court that "the Act imposes [on them] not only a positive duty to seek out and remedy violations when they occur but also, and primarily, *a duty to implement measures that will insure that violations will not occur.*"[11]

If the court of appeals interpretation is allowed to stand, there is no way that the stern strictures of this Court's

[10]United States v. Park, 421 U.S. 658 (1975).

[11]*Id.* at 672 (emphasis added). The tension between the teaching of *Park* and the opinion below gives rise to significant constitutional questions. *Cf.* Lambert v. California, 355 U.S. 225, 229 (1957):

> "As Holmes wrote in The Common Law, 'A law which punished conduct which would not be blameworthy in the average member of the community would be too severe for that community to bear.' *Id.*, at 50. Its severity lies in the absence of an opportunity either to avoid the consequences of the law or to defend any prosecution brought under it."

opinion in *Park* can be reconciled with the practical need to continue production and distribution of the food supply while the FDA, the industry, and the public are working their way through costly and time-consuming trial-type hearings for each one of the currently listed and the many unlisted environmental contaminants in virtually all raw agricultural products. The Government's Petition documents the literal impossibility of the FDA's initiating and completing within the foreseeable future proceedings for the establishment of formal tolerances for all detectable environmental contaminants. (Pet. 15-16).

The court below was apparently unaware of the protracted rulemaking procedures that must be observed in the promulgation of § 406 tolerances for each contaminant and for each food commodity. In describing the nature of the case, the court stated that the plaintiffs "brought suit in federal district court to require the FDA to adopt, *by way of notice-and-comment rulemaking*, formal aflatoxin levels or 'tolerances,' as opposed to informally implemented action levels." (Pet. App. 2a) (emphasis added). The fact is that § 406 tolerances may not be adopted by way of simple notice-and-comment rulemaking under § 701(a),[12] but instead may be adopted only pursuant to the far more complex and protracted procedures prescribed in § 701(e). These are, to be sure, initiated by notice and comment, but they also include an evidentiary hearing and the other time-consuming features of a determination that is required to be on the record, if such a determination is demanded by any person who will be adversely affected.[13] Whatever may be

[12]21 U.S.C. § 371(a), which vests in the Secretary "authority to promulgate regulations for the efficient enforcement of the Act." *See, e.g.*, Abbott Laboratories v. Gardner, 387 U.S. 136, 138 (1967).

[13]21 U.S.C. § 371(e), which provides in relevant part that, "Any action for the issuance, amendment, or repeal of any regulation under section . . . 346 . . . of this Act shall be begun by a proposal" that initiates the full procedures of 21 U.S.C. § 371(e), (f) and (g).

said for the wisdom or efficiency of these rulemaking-on-a-record procedures, there can be no doubt that the process necessarily entails a substantial investment in time and resources by FDA and the interested public.[14]

In view of the total impracticability of § 406 tolerances being promulgated for all unavoidable environmental contaminants within the next few years, if ever, this case thus involves far more than a question of the particular rulemaking procedures employed by FDA. At the heart of the case is a substantive issue of law that bears importantly on the administration of the Act, the integrity of the nation's food supply, and the criminality of the everyday practices of thousands of food companies and their responsible officials.

II. THE QUESTION PRESENTED BY THE PETITION IS SUBSTANTIAL

The basic conclusion upon which the opinion below rests is that the aflatoxin action levels at issue are invalid because the Act does not "allow the shipment of aflatoxin-tainted corn without the establishment of a tolerance."[15] The court of appeals justified this conclusion almost solely on the ground that the "presence of the critical word 'shall' [in the

[14]*See, e.g.*, National Nutritional Foods Ass'n v. FDA, 504 F.2d 761 (2d Cir. 1974), *cert. denied*, 420 U.S. 946 (1975); Merrill and Hutt, *Food and Drug Law* 895-96 (1980); Hamilton, *Rulemaking on A Record by the Food and Drug Administration*, 50 Tex. L. Rev. 1132 (1972); Note, *FDA Rule-Making Hearings: A Way Out of the Peanut Butter Quagmire*, 40 Geo. Wash. L. Rev. 726 (1972); Administrative Conference of the United States, Recommendation No. 71-7, 2 Recommendations and Reports of the Administrative Conference of the United States 42 (1973); Austern, *Is Government by Exhortation Desirable?*, 22 FDC L.J. 647 (1967); Pendergast, *The Nature of Section 701 Hearings and Suggestions for Improving the Procedures for the Conduct of Such Hearings*, 24 FDC L.J. 527 (1969).

[15]Pet. App. 8a. See also the excerpts from the opinion cited at p. 5 n. 3, *supra*.

second clause of § 406] suggests a directive to the Secretary to establish a tolerance, if a food with an unavoidable poisonous or deleterious substance is to be considered unadulterated." (Pet. App. 6a).

Before turning to the fundamental error in the court's reading of the Act, it may be helpful to review the language of §§ 402(a) and 406 as it has been interpreted by FDA and understood by the affected industry since its enactment in 1938. The first clause of § 402(a)(1) states the general standard that a food shall be deemed adulterated if it contains any poisonous or deleterious substance which may render it injurious to health. This Court has held that under this language the poisonous or deleterious substance must be present in sufficient quantity that it might make the food injurious to health.[16] Thus, quantitative action levels are wholly appropriate as agency guidelines for the enforcement of § 402(a)(1). Because the second clause of § 402(a)(1) prescribes a somewhat more lenient standard for poisonous or deleterious substances that are "not added,"[17] the first clause applies only to "added" poisonous or deleterious substances.[18]

[16]In United States v. Lexington Mill & Elevator Co., 232 U.S. 399, 410-11 (1914), the Supreme Court held that under the 1906 Act the simple existence of an added poisonous or deleterious substance in a food did not render the food adulterated. The substance must be shown to be present in such quantity that might render the product injurious to health. In Flemming v. Florida Citrus Exchange, 358 U.S. 153, 161 (1958), this Court held that the rule of *Lexington Mill* continued to apply under the first clause of § 402(a)(1).

[17]The second clause provides that "in case the substance is not an added substance such food shall not be considered adulterated under this clause if the quantity of such substance in such food does not *ordinarily* render it injurious to health." 21 U.S.C. § 342(a)(1) (emphasis added).

[18]The difference between "added" and "not added" substances is discussed at p. 6, *supra*.

For a few categories of added poisonous or deleterious substances this general safety standard in the first clause of § 402(a)(1) is explicitly displaced by a more specific standard contained elsewhere in the statute.[19] In addition, § 402(a)(2)(A) provides that food is deemed adulterated if it contains "any added poisonous or deleterious substance . . . which is unsafe within the meaning of section 406."[20] This latter section provides that an added poisonous or deleterious substance shall be deemed to be "unsafe" for purposes of § 402(a)(2)(A) under two circumstances: under the first clause of § 406, *any* amount of such a substance is unsafe if it is *not* required in the production of the food or is *not* unavoidable; and under the third clause of § 406, if a tolerance has been adopted for an added poisonous or deleterious substance that *is* required in production or *is* unavoidable, the substance is deemed unsafe if it exceeds the amount prescribed in the tolerance. While a tolerance is in effect, a food containing the substance is not considered adulterated under the general safety standard of § 402(a)(1).[21]

On its face § 406 prescribes no safety standard for required or unavoidable added poisonous or deleterious sub-

[19]More specific statutory standards are prescribed in §§ 402(a)(2)(B) and 408 for registered pesticides in foods; in §§ 402(a)(2)(C) and 409 for food additives in foods, in § § 402(c) and 706 for color additives; and in §§ 402(a)(2)(D) and 512 for new animal drugs. 21 U.S.C. §§ 342, 346a, 348, 376, and 360b. These substances are also excluded from § 402(a)(2)(A).

[20]Sections 402(a)(1) and 402(a)(2)(A) thus both apply to added poisonous or deleterious substances not otherwise excluded, but they prescribed different tests of adulteration, and the latter applies *only* when § 406 explicitly deems a substance to be unsafe.

[21]This provision has the effect of avoiding a conflict between the somewhat different safety standards in §§ 402(a)(1) and 406, if the prescribed tolerance is higher than the level that would be permitted under § 402(a)(1).

stances for which a tolerance has not been promulgated. To repeat, § 402(a)(2)(A) treats a food as adulterated only if it contains a substance "which is unsafe within the meaning of section 406." Section 406 explicitly sets forth only two circumstances in which an added substance is deemed to be "unsafe," neither of which applies to required or unavoidable substances for which no tolerance has been prescribed. This apparently deliberate omission does not leave a regulatory gap, however, since the general standard for added poisonous or deleterious substances in the first clause of § 402(a)(1) remains applicable to substances not covered by § 406 or by a more specific statutory standard.

The court of appeals interpretation of these statutory provisions derives from the directive in the second clause of § 406 that "the Secretary shall promulgate regulations" limiting the quantity of a required or unavoidable added substance in a food "to such extent as he finds necessary for the protection of public health."[22] The use of "shall," the court states, "plainly suggests a directive to the Secretary to establish a tolerance, if a food with an unavoidable poisonous or deleterious substance is to be considered unadulterated."[23] But the language of § 406 simply does not

[22]As made clear in the Petition, the "to such extent" clause may reasonably be read as either a precondition for the adoption of a tolerance (the FDA interpretation) or as a prescription of the level to be adopted (the court of appeals interpretation). (Pet. 8). But even if the court of appeals interpretation is accepted in this respect, so that the Secretary is directed to prescribe a tolerance for *every* unavoidable environmental contaminant, nothing in § 406 or elsewhere in the Act supports the court's conclusion that in the absence of a tolerance § 402(a)(1) must be totally disregarded and that any detectable amount of an environmental contaminant renders a food adulterated.

[23]Pet. App. 6a (emphasis added). The court's use of "suggests" apparently reflects its recognition that § 406 does not on its face state that an added required or unavoidable substance is unsafe in the absence of a tolerance, but the opinion does not otherwise attempt to deal with this statutory omission.

say that a food is adulterated or unsafe if it contains an added unavoidable substance for which no tolerance is in effect. The court reads such a requirement into § 406, and in doing so reads the first clause of § 402(a)(1) out of the Act altogether, for this latter provision is of no effect whatever if all added poisonous or deleterious substances — whether or not required or unavoidable, and whether or not a tolerance has been prescribed — are governed by §§ 406 and 402(a)(2)(A).[24] The court's interpretation clearly offends the "well-settled rule that all parts of a statute, if possible, are to be given effect." *American Textile Manufacturers Institute, Inc. v. Donovan*, 452 U.S. 490, 513 (1981); *Fidelity Federal Savings & Loan Association v. De La Cuesta*, 458 U.S. 141, 163 (1982).

The court of appeals purported to find support for its reading of § 406 in the "overall structure" of the section, and in particular in the second sentence, which in the court's words provides "that, when a regulation establishing a tolerance is in effect, such food will not be considered adulterated." (Pet. App. 7a). On this basis, the court concluded:

> "Since the existence of a regulation operates to render the food legally unadulterated, the statute, in our view, plainly requires the establishment by regulation of tolerances before aflatoxin-tainted corn may lawfully be shipped in interstate commerce." *Id.*

In both of these quoted excerpts the court's paraphrases of the second sentence of § 406 omitted the concluding phrase of that sentence — "within the meaning of clause (1)

[24]If § 402(a)(1) was intended by Congress to apply only to "not added" substances, the section would have been written without the first clause. Particularly since Congress enacted § 402(a)(1) in this form and § 406 at the same time (in 1938), it is unreasonable to conclude that Congress intended for § 406 to render the first clause of § 402(a)(1) totally ineffective.

of section 402(a)."[25] This omission was apparently not inadvertent, for when the court earlier quoted § 406 at length in its opinion, it elided from the second sentence the phrase "within the meaning of clause (1) of section 342(a) of this title." (Pet. App. 4a). This suggests that the court simply did not fully understand the statutory scheme. The ultimate standard for a food is adulteration. The mere existence of a formal tolerance level for a contaminant, of course, does not prevent a food containing any quantity of the contaminant from being adulterated. If the tolerance level is exceeded, the contaminant is "unsafe" under § 406 and therefore the food is adulterated under § 402(a)(2). The statute provides that the food is not adulterated under § 402(a)(1) if a tolerance is in effect in order to assure that a food will not be deemed adulterated *under § 402(a)(1)* when the contaminant level in the food is at or below that prescribed in a § 406 tolerance.

The court's misunderstanding may have contributed to the basic logical fallacy in the indented sentence quoted above. From the statement, "If a tolerance *is* in effect, then a food containing the substance *shall not* be considered adulterated" (if A, then not B), the court infers "A tolerance *is not* in effect, therefore a food containing the substance *shall* be considered adulterated" (not A, therefore B). The major premise is wrong because it misstates the statute. And the laws of logic in any event deny the validity of the court's inference[26] and confirm the statutory interpretation

[25]The second sentence reads in full: "While such a regulation is in effect limiting the quantity of any such substance in the case of any food, such food shall not, by reason of bearing or containing any added amount of such substance, be considered to be adulterated within the meaning of clause (1) of section 402(a)."

[26]An argument of this form is said to commit the Fallacy of Denying the Antecedent. Copi, *Introduction to Logic*, 234, 274 (1972).

that if no tolerance is in effect for an unavoidable added substance, § 406 does not apply and the general safety standard of § 402(a)(1) governs.

The court of appeals interprets § 406 as if it provided that an added unavoidable poisonous or deleterious substance shall be deemed unsafe *unless* a tolerance is in effect. But when Congress has intended to impose such a requirement, it has done so explicitly, not by implication or "suggestion." Sections 408(a), 409(a), and 706(a) provide that a pesticide, or a food additive, or a color additive shall be deemed to be unsafe "unless" a lawfully prescribed tolerance or exemption is in effect.[27] The wording of each of these provisions indicates that they were to some extent modeled on the language of § 406, but in each case the "unless" clause — not present in § 406 — was added. The court of appeals opinion

[27]21 U.S.C. §§ 346a(a), 348(a), 376(a). The regulatory regimes of §§ 408, 409 and 706 were enacted by Congress to establish premarket approval systems for these three categories of deliberately used or added substances, and it was thus important to provide that the presence of one of these substances in a food without a tolerance being effective would render a food adulterated. Each of these amendments necessitated the creation of an elaborate bureaucratic machinery and the promulgation of literally hundreds of regulations set forth in a total of more than 750 pages of the Code of Federal Regulations. 40 C.F.R. Part 180, pp. 216-379 (tolerances for registered pesticides deliberately used on raw agricultural commodities); 21 C.F.R. Parts 170-193, pp. 5-494 (food additive regulations); 21 C.F.R. Parts 70, 71, 73, 74, 80, 81, 82, pp. 229-341 (color additive regulations). The court of appeals opinion would require the creation of a similar bureaucracy and the promulgation of an equivalent volume of regulations for environmental contaminants if the unavoidable presence of these substances in foods is to be legitimized. As previously noted, the only alternatives would be for food companies to halt the production and shipment of most foods, or to ship adulterated foods knowingly and deliberately — a practice which this Court has severely warned against in the *Park* case. *See* p. 9, *supra*.

does what Congress deliberately decided not to do — interpret § 406 as if it read exactly like §§ 408(a), 409(a), and 706(a).

In summary, as interpreted by FDA the general safety standard in the first clause of § 402(a)(1) remains applicable to any required or unavoidable added poisonous or deleterious substance — such as an environmental contaminant — for which a tolerance has *not* been prescribed under § 406[28] (and which is not subject to the more specific standards of §§ 408, 409, 706 or 512). If the FDA can demonstrate in court that a food contains an amount of such a substance which may render the food injurious to health, the food will be deemed to be adulterated and subject to appropriate enforcement action. If the amount of such substance in a food is below the amount that may render it injurious to health, the product is lawful. The action levels promulgated by the FDA for certain environmental contaminants provide notice to the industry and the public of the amounts of such substances in food above which enforcement action will be taken under § 402(a)(1).[29]

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[28]"[T]he act clearly contemplates that the Government may proceed against a contaminated food under section 402(a)(1) of the act when no tolerance is effective." 42 Fed. Reg. 52818 (Sep. 30, 1977). The legislative history set forth in the Government's Petition demonstrates that the FDA interpretation of the Act was shared by Congress and the food industry, including the National Canners Association and its counsel. (Pet. 11-12 n.5).

[29]*See* Judge Frank's persuasive dissent in United States v. 449 Cases, etc., 212 F.2d 567, 575 (2d Cir. 1954), as to the importance of providing public notice of enforcement standards. The action levels promulgated by FDA generally reflect the agency's judgment as to what amount of a contaminant may render a food injurious to health. In some instances they also take into account the unavoidability of the substance and are thus a reflection of the agency's enforcement discretion under § 306, 21 U.S.C. § 336. *See* 39 Fed. Reg. 42745 (Dec. 6, 1974) (third column).

The court of appeals decision below totally disrupts this carefully wrought statutory scheme and should not be permitted to stand.

CONCLUSION

For the foregoing reasons, the Petition for Writ of Certiorari should be granted.

Respectfully submitted,

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